

RECEIVED
CENTRAL FAX CENTER

JUL 18 2006

5

Docket No. ALL-T101D1
Serial No. 10/643,298Remarks

Claims 1-3, 5-9 and 11-15 were pending in the subject patent application. By this amendment, claims 1, 3, 5, 6, 8, 9, 11 and 12 have been amended. Support for the amendments can be found throughout the specification. No new matter has been added by this Amendment. Accordingly, claims 1-3, 5-9 and 11-15 remain before the Examiner for consideration.

The amendments set forth herein should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

As an initial matter, the Declaration and Power of Attorney form has been objected to for not adequately identifying the correct claim of priority. In order to correct the typographical error the applicant has attached herewith an Application Data Sheet to correct the typographical error pursuant to 37 CFR 1.76(d)(1)-(4). Reconsideration and withdrawal of this objection is respectfully requested.

The applicant wishes to thank Examiners Royds and Marschel for the courtesy extended to the undersigned and James Parker during the personal Examiner Interview conducted July 12, 2006. This response and the amendments set forth herein are submitted in accordance with, and constitute a summary of, the substance of that interview.

Claim 1 has been rejected under 35 U.S.C. §102(b) as being anticipated by Winitz (U.S. Patent No. 3,697,287). The applicant respectfully traverses this ground of rejection to the extent that it might be applied to the current claims because the cited reference does not disclose the applicant's unique composition.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIII Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution

J:\sh-resp\all\ALL-T101D1E.amendment.doc\la

history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIII, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

Please note that, unlike the Winitz composition, the essential amino acid component of the composition of the current invention is only arginine, leucine, isoleucine and valine. By contrast, the Winitz reference discloses compositions with many additional amino acids. Thus, Winitz does not disclose, within its four corners, all of the elements of the claimed invention. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

Claims 1-3 and 5 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Winitz (U.S. Patent No. 3,697,287) in view of Durst (U.S. Patent No. 3,434,843) and Millman (U.S. Patent No. 4,871,550). The applicant respectfully traverses this ground for rejection to the extent that it might be applied to the claims now presented for examination.

As discussed during the recent Examiner interview, the applicant understands that the outstanding rejection was based on the interpretation of “consisting essentially of” as being the same as “comprising.” To address this issue, the applicant has now amended the claims to recite that the essential amino acids “consist of” only the four recited amino acids.

The shortcomings of the Winitz reference with respect to the current invention have been discussed above. The secondary Durst and Millman references do not cure these deficiencies. Specifically, the cited references are not addressing the problem addressed by the current invention -- stimulating muscle growth in a palatable, efficient and metabolically favorable way. Thus, there would be no motivation to modify the Winitz composition to arrive at the composition of the current invention. Without such a motivation, and an expectation of success, the claimed invention cannot be said to be obvious.

Please note that each of the cited references disclose compositions with many additional amino acids. An advantageous composition having only the four specific essential amino acids is not suggested by the cited references.

The applicant respectfully submits that the cited references, even when combined, do not disclose or suggest, or provide any motivation to arrive at, the applicant's unique muscle-

stimulating composition having only the specifically selected and identified amino acids. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103 based on Winitz in combination with Durst and Millman.

Claims 6-9 and 11-15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rudman *et al.* (Growth hormone Treatment of Fraility in Men over 60, *New England Journal of Medicine*, 1990); Dudrick *et al.* (U.S. Patent No. 5,026,721) and Boynton *et al.* (U.S. Patent No. 5,087,624). The applicant respectfully traverses this ground for rejection because the cited references, alone or in combination, do not disclose or suggest the use of the applicant's specific composition to stimulate muscle growth or enhance immunity.

Surprisingly, the current inventor has found that a composition with only four specific amino acids is highly effective in promoting muscle growth. This particular formulation is quite unexpected because, for example, it does not include lysine and, at the time of the invention, those skilled in the art believed that arginine should be combined with lysine.

Specifically, a noted disadvantage associated with L-arginine is that when administered on its own, arginine tends to promote herpes 1 and 2, which gives rise, amongst other adverse effects, to mouth sores and genital discomfort. It is known that L-lysine inhibits the growth of such viruses, and so lysine is conventionally administered with arginine to minimize the onset of herpes.

It has been discovered, surprisingly, according to the present invention that it is possible to administer L-arginine in the present composition with only three other essential amino acids, and without lysine. This is contrary to the conventional wisdom that existed at the time of the present invention. The claims now presented in this application exclude the presence of lysine.

The references to Dudrick *et al.* and Boynton *et al.* do not cure the deficiencies of the primary Pearson *et al.* (Rudman) reference. For example, Dudrick *et al.* provide an amino acid supplement comprising, as "primary" amino acids, arginine, leucine, valine and lysine (column 2, lines 48-50). Thus, if anything, Dudrick *et al.* teach away from the current invention. Boynton does not address this issue at all.

The Millman and Winitz references (discussed above) also include lysine in addition to arginine. In light of the above teachings, it is clear that a person of ordinary skill, given the

J:\sh-res\pl\ALL-T101D1F.amendment doc\la

combination of Rudman *et al.*, Dudrick *et al.* and Boynton, would have been motivated at the date of the present invention to include L-lysine with L-arginine. In the present invention, lysine is specifically excluded.

The applicant further respectfully submits that there is no disclosure in Rudman *et al.* (or the other references) suggesting the combined use of leucine, isoleucine and valine.

The applicant respectfully submits that there is nothing in the cited art which would motivate the skilled artisan to produce the specific, unique and advantageous composition as currently claimed. Accordingly, in view of the foregoing remarks, reconsideration and withdrawal of the rejection under 35 U.S.C., 103 based on the cited references is respectfully requested.

J:\sh-resp\AIL-T1011D1F.amendment.doc\la

9

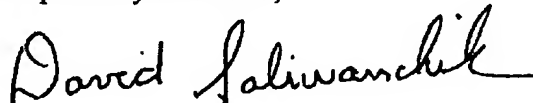
Docket No. AIL-T101D1
Serial No. 10/643,298

In view of the foregoing remarks and the amendments above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



David R. Saliwanchik
Patent Attorney
Registration No. 31,794
Phone: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

DRS/la

Attachment: Application Data Sheet (ADS)

J:\sh-respl\AIL-T101D1F amendment.doc\la